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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,362	09/16/2003	Roger Massengale	IFLOW.149A	1650

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EXAMINER	
KOHARSKI, CHRISTOPHER	
ART UNIT	PAPER NUMBER
3763	

NOTIFICATION DATE	DELIVERY MODE
04/21/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/663,362	MASSENGALE ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER D. KOHARSKI	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 January 0208*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5-16 and 25-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5-16 and 25-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/05/2007*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Examiner acknowledges the reply filed 1/07/2008 in which claim 1 was amended and new claims 28-31 were added. Currently claims 1-2, 5-16 and 25-31 are pending for examination in this application.

Information Disclosure Statement

The information disclosure statement (IDS) that was submitted on 10/05/2007 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 5, 7-9, 12-15, 26-29 and 31 are rejected under 35 U.S.C. 102(b) as being anticipated by Reed, Jr. (5,827,530). Reed, Jr. fillable patch for dermal or transdermal delivery.

Regarding claims 1, 5, 26-29 and 31, Reed, Jr. discloses a fluid medication delivery device (11), comprising: a fluid impermeable layer (42); a fluid semi-permeable layer (18), said semi-permeable layer and said impermeable layer cooperating to define a space therebetween, said space defining a fluid reservoir of said delivery device (57), said semi-permeable layer and said impermeable layer having a continuous seal

therebetween (via sidewall 23) to define a periphery of said fluid reservoir; at least one internal wall (52) within said fluid reservoir configured so as to form multiple interconnected regions within said fluid reservoir, said internal wall formed by securing a portion of said fluid impermeable layer (edge 20) to a portion of said fluid semi-permeable layer (edge 18, via side wall 23) to form multiple linear seam portions; a fluid inlet communicating (49) with said fluid reservoir, said fluid inlet comprising a valve configured to permit fluid entry into said fluid reservoir (via 48), said fluid inlet adapted to permit said delivery device to be selectively connectable to a connector for a supply of fluid (50), said delivery device adapted to selectively secure said connector in the radial and axial direction, wherein said valve comprises a one-way valve configured to permit fluid to enter said fluid reservoir and to prevent fluid from exiting said fluid reservoir through said fluid inlet (col 5, ln 1-15); and wherein a fluid is diffusable across said semi-permeable layer in response to a pressure imparted on said fluid (Figures 1-5, cols 1-2).

Regarding claims 7-9 and 12-15, Reed, Jr. discloses a fluid medication delivery device (10), comprising: a fluid impermeable pouch having first (22) and second opposing walls (18), said first wall (22) and said second wall (18) defining a space therebetween, said space defining a fluid reservoir (24) of said delivery device, said second wall (18) including a plurality of openings therethrough defining a diffusion area of said delivery device; a fluid inlet (37) communicating with said fluid reservoir, said fluid inlet comprising a valve configured to permit fluid entry into said fluid reservoir (col 3, ln 50-65), said fluid inlet adapted to permit connection to a connector for a supply of fluid (38), said fluid inlet adapted to selectively secure said connector in the radial and

axial direction; and a fluid semi-permeable layer (12) covering at least said diffusion area of said delivery device, said semi-permeable layer being configured such that fluid within said fluid reservoir must pass through said semi-permeable layer before exiting said delivery device, wherein said fluid inlet (32) comprises a one-way valve configured to permit fluid entry into said fluid reservoir (col 3, ln 50-65), wherein a fluid is diffusable across said semi-permeable layer in response to a pressure imparted on said fluid by an external source of fluid pressure (Figurers 1-5, cols 1-2).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 2, 6, 10-11 and 16 are rejected under 35 U.S.C 103(a) as being unpatentable over Reed, Jr. in view of Deniega et al. (6,350,253). Reed, Jr. meets the claim limitations as described above except for the specific membrane pore sizes and membrane materials.

However, Deniega et al. teaches a catheter for uniform introduction of medication.

Regarding claims 2, 6, 10-11 and 16, Deniega et al. teaches a drug delivery device (20) catheter comprising a catheter (24) for long-term continuous delivery of medication (36) comprising a semi-permeable membrane with varying pore sizes from 0.1 microns to 1.2 microns (col 8, ln 5-30) composed of several materials including polysulfone, polyethersulfone, nylon, and polyvinylidene di-flouride (col 7, 65-70, col 8, ln 1-5) (Figures 1 and 5-6).

At the time of the invention, it would have been obvious to use the membrane materials of Deniega et al. with the system of Reed, Jr. in order to use an advantageous membrane to minimize the flow of bacteria into the reservoir and allow for optimal drug delivery. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Deniega et al. (cols 1-2).

Claim Rejections - 35 USC § 103

Claims 25 and 30 is rejected under 35 U.S.C 103(a) as being unpatentable over Reed, Jr. in view of Weston et al. (4,605,309). Reed, Jr. meets the claim limitations as described above except for the luer coupler connector on the fluid medication delivery device and a curvilinear seal.

However, Weston et al. teaches a transdermal infusion device.

Regarding claims 25 and 30, Weston et al. teaches a transdermal patch (12) for with a semi-permable layer (15) (Figure 3) and fluid impermable pouch (10,16) connected with a curvilinear seal (Figures 2-5) with a fluid inlet (24) connected to a connector (18) which is a luer connector (Figures 1-5).

At the time of the invention, it would have been obvious to add the luer connector and circular shape of Weston to the system of Reed, Jr. in order to add a readily connectable universal well known connector for fluid transfer. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Weston et al. (cols 1-2). Additionally, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Reed, Jr. in a circular shape, since it has been held the variations in shape were a matter of choice and only involves routine skill in the art. See *In re Dailey*, 357 F.2d 669, 149 USPQ (CCPA 1966).

Response to Arguments

Applicant's arguments filed 1/07/2008 have been fully considered but they are not persuasive. Applicant's Representative asserts that the Reed, Jr. reference does not disclose a second side wall as claimed by Applicant.

Examiner has fully considered applicant's arguments but they are not persuasive. It is examiners position that given a careful reading, the claims do not distinguish over the prior art of record.

Examiner asserts that the Reed, Jr. reference discloses a delivery device which contains several discrete wall portions as described above (42, 18, 12, 23, 14) which meet the claimed limitation as described above.

The prior art of record teaches all elements as claimed and these elements satisfy all structural, functional, operational, and spatial limitations currently in the claims. Therefore the standing rejections are proper and maintained.

Suggested Subject Matter

The following claim subject matter is suggested by the examiner and considered to distinguish patentably over the art of record in this application and is therefore presented to Applicant for consideration:

Examiner suggests further clarification of the seam portions and to which specific layers each is directly attached to (see Applicant's Figures 7-8).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Date: 4/1/2008

/Christopher D Koharski/
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763